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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,923	04/30/2001	Patrick Kennedy	1022-11	4246

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EXAMINER

LEITH, PATRICIA A

ART UNIT PAPER NUMBER

1655

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/845,923

Applicant(s)

KENNEDY, PATRICK

Examiner

Patricia Leith

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-22, 24-28 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-8, 10-19, 21, 22, 24-28 and 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/6/05 has been entered.

Claims 1-8, 10-22, 24-28 and 30-33 are pending in the application.

Claims 1-3 and 20 were previously withdrawn from the merits as they are directed toward a non-elected invention.

Claims 4-8, 10-19, 21-22, 24-28 and 30-33 were examined on their merits.

The Declaration of Inventor Patrick Kennedy filed 9/6/05 was taken fully into account and will be discussed *infra* under the 112 First paragraph rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 6-8, 10-11, 13-19, 21-22, 24-28 and 30-33 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition and method for relieving itch, pain and swelling with certain abrasive ingredients, a carrier and certain anti-itch enzymes, does not reasonably provide enablement for a composition and method as such with any anti-itch enzyme or without the addition of an enzyme. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed

invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

In the Instant case, Applicant is claiming that only an abrasive ingredient along with a carrier; or alternatively, wherein any abrasive ingredient and any carrier, or an

abrasive ingredient, a carrier and any anti-itch enzyme will 'relieve any of the itch , pain and swelling caused by the insect bites and stings' as recited by the claims.

There is no indication in the Instant specification as filed that any of the compositions without the specifically shown enzymes such as papain, will actually have any effect on itch or pain caused by an insect bite or sting. The Instant specification does not provide any evidence that an abrasive ingredient alone, or in combination with a carrier would actually provide for the effect as indicated by the claims.

There are no working examples in the Instant specification. Thus, one must turn to the state of the art in order to determine the predictability of the composition.

Abrasive ingredients were not known in the art for treating pain or itch associated with an insect sting or bite. Abrasive ingredients are not known to have any medicinal effect toward the inflammatory response which follows an insect bite. Thus, it is deemed that abrasive ingredient which is not known for having these effects, admixed with a carrier is also not enabled because it is deemed that a simple carrier such as vegetable oil would not provide for any beneficial effects.

The Declaration of Inventor Patrick Kennedy filed 9/6/05 was taken fully into account. However, the information found in the Declaration is not commensurate in scope with the claimed invention. The Inventor did not state what composition was

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actually effective or that certain embodiments of the claims that do not state all of the active ingredients will actually provide for the claimed effect.

*In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that:

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, **he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art**; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (emphasis added)

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 10-11, 21-22, 24-25, 30-31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by The Daily Telegraph (TDT) (1996).

TDT (1996) reported that 'Apricot Body Scrub' sold by Boots Natural Collection comprised peach kernel shell and apricot kernel oil (see page 1).

Thus, TDT anticipated the claims.

As for the intended use of the composition, Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). When the claim recites using an old composition or structure and the use is directed to a result or property of that composition or structure, then the claim is anticipated (MPEP 2100 pp. 2113).

Claims 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Someya (JP361040211A).

Someya (JP361040211A) disclosed a bathing agent comprising a protease such as papain blended with sodium chloride and ethanol (see English Abstract). Sodium chloride exists as crystals in its solid form. Thus, sodium chloride; salt, is considered an 'abrasive ingredient'.

As for the intended use of the composition, Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). When the claim recites using an old composition or structure and the use is directed to a result or property of that composition or structure, then the claim is anticipated (MPEP 2100 pp. 2113).



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 6-8, 10-11, 21-28 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over TDT (1996).

The teachings of TDT were discussed *supra*. TDT did not specifically teach wherein the composition was in the form of a lotion, paste or liquid or wherein the composition was present in an aqueous pharmaceutical carrier.

Although the reference did not specifically teach wherein the composition was in the form of a paste, powder or lotion, or wherein an aqueous pharmaceutical carrier was present, one of ordinary skill in the art would have been motivated to manufacture different forms of the bath composition in order to suit individual needs. It was routine in the art to formulate products into different forms in order to increase marketability of the product.

Claims 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Someya (JP361040211A ) in view of Kerr (1998).

The teachings of Someya were discussed *supra*. Someya did not specifically disclose the incorporation of an active ingredient such as plant oil or wherein the composition was in the form of a lotion or a paste or a powder.

Plant oils were well known in the art to be used in bath preparations. For example, Kerr, reporting for The Herald , indicated that lavender oil was known to be used in bath preparations, especially for its relaxing properties (thus, lavender oil is considered to be an 'active ingredient')(see p. 1).

One of ordinary skill in the art would have been motivated to add lavender oil to the bath composition as taught by Someya in order to impart a relaxing scent to the bath composition. It was clear from the prior art that plant oils were used in bathing; thus, the ordinary artisan would have had a reasonable expectation that the addition of known bathing oils such as lavender oil would have been an advantageous addition to the bath composition as disclosed by Someya.

Although neither reference specifically taught wherein the composition was in the form of a paste, powder or lotion, one of ordinary skill in the art would have been motivated to manufacture different forms of the bath composition in order to suit individual needs.

Claims 5 and 12 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

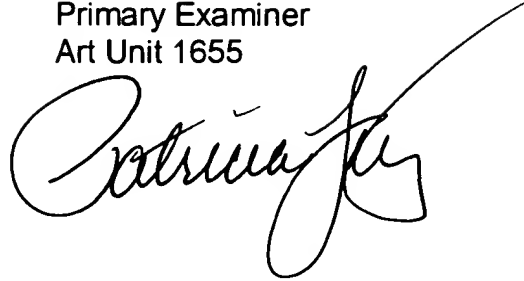
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Patricia Leith  
Primary Examiner  
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February 16, 2006

A handwritten signature in black ink, appearing to read "Patricia Leith", with a long, sweeping flourish extending from the end of the name.